UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC., Plaintiffs, -v- SERENITY PHARMACEUTICALS, LLC, and REPRISE BIOPHARMACEUTICS, LLC, Defendants.	No. 17-cv-9922 (RWS) ECF CASE **FILED UNDER SEAL**

SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, and AVADEL SPECIALTY PHARMACEUTICALS, LLC, Counterclaim-Plaintiffs, -v- FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC., Counterclaim-Defendants.	No. 17-cv-9922 (RWS) ECF CASE **FILED UNDER SEAL**

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

Defendants Serenity Pharmaceuticals, LLC ("Serenity") and Reprise Biopharmaceutics, LLC ("Reprise") (collectively, "Defendants"), by and through their undersigned counsel, hereby submit their Answer and Affirmative Defenses to the Amended Complaint for Declaratory Judgment (D.I. 18) ("FAC") filed by Ferring Pharmaceuticals Inc., Ferring B.V., and Ferring

International Center S.A. (collectively, "Ferring" or "Plaintiffs") on June 30, 2017 in C.A. No. 17-cv-479-GMS (D. Del.), which case was transferred to this Judicial District as the above-captioned action on December 20, 2017. Defendants submit their Answer and Affirmative Defenses to the FAC in accordance with the numbered paragraphs thereof, as follows. To the extent the unnumbered headings of the FAC contain allegations supporting Plaintiffs' claims, they are denied. Defendants further deny all allegations of the FAC that are not expressly admitted below.

Further, Defendants and Avadel Specialty Pharmaceuticals, LLC ("Avadel") (collectively with Defendants, "Counterclaimants"), by and through their undersigned counsel, hereby submit their Counterclaims to the FAC.

THE PARTIES

1. Admitted, on information and belief.

2. Admitted, on information and belief.

3. Admitted, on information and belief.

4. Admitted, on information and belief.

5. Admitted.

6. Admitted that Serenity develops products that address urinary conditions, and that the U.S. Food and Drug Administration ("FDA") approved NDA No. 201656 ("Serenity's NDA") for *NOCTIVA* (desmopressin acetate) nasal spray for the treatment of nocturia. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 6 of the FAC.

7. Admitted.

8. Admitted that Dr. Seymour Fein ("Fein") and Dr. Ronald V. Nardi ("Nardi") are equity participants and principals of Reprise. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 8 of the FAC.

9. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 9 of the FAC and, therefore, deny them.

PERSONAL JURISDICTION AND VENUE

10. Paragraph 10 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 10 of the FAC.

Personal Jurisdiction over Serenity

11. Paragraph 11 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 11 of the FAC.

Personal Jurisdiction over Allergan

12. Paragraph 12 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 12 of the FAC and, therefore, deny them.

13. Paragraph 13 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 13 of the FAC and, therefore, deny them.

Personal Jurisdiction over Reprise

14. Defendants state that whether Serenity Pharmaceuticals Corp. is "the predecessor of Defendant Serenity" is a legal conclusion to which no response is required. Admitted that Fein is the inventor of, *inter alia*, United States Patent No. 7,405,203 (the "'203 patent"); 7,579,321 (the "'321 patent"); and 7,799,761 (the "'761 patent") (collectively, the "Patents in Suit"), that

Serenity Pharmaceuticals Corp. was formed under the laws of Delaware on December 13, 2006, and that Reprise was formed under the laws of New York on January 2, 2007. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 14 of the FAC and expressly note that this case was transferred from the District of Delaware to this Judicial District on December 20, 2017.

15. Admitted.

16. Denied.

17. Defendants state that whether Serenity is "the successor-in-interest to Serenity Pharmaceuticals Corp." is a legal conclusion to which no response is required. Admitted that Serenity was formed under the laws of Delaware in November 2009, and that Serenity is an exclusive licensee of the Patents in Suit. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 17 of the FAC and expressly note that this case was transferred from the District of Delaware to this Judicial District on December 20, 2017.

18. Admitted that Serenity and Reprise entered into an agreement with Allergan Sales, LLC and Allergan, Inc. (collectively, "Allergan") on March 31, 2010 (the "Three-Way Agreement) and that a copy of what purports to be a redacted version of the Three-Way Agreement was attached to the FAC as Exhibit A. To the extent that Paragraph 18 of the FAC purports to quote from, summarize, describe, or make allegations concerning the Three-Way Agreement, Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 18 of the FAC.

19. Admitted.

20. Admitted that Serenity issued a press release on March 6, 2017, and that a copy of what purports to be Serenity's March 6, 2017 press release was attached to the FAC as Exhibit B. To the extent that Paragraph 20 of the FAC purports to quote from, summarize, describe, or make allegations concerning Serenity's March 6, 2017 press release, the Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of the document and its contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 20 of the FAC.

21. Admitted.

22. Denied.

23. Admitted.

24. Paragraph 24 of the FAC sets forth legal conclusions to which no response is required. To the extent a response is required, admitted that Fein is an equity participant and principal of Reprise, and that Fein is an equity participant and Chief Medical Officer of Serenity. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 24 of the FAC.

25. Paragraph 25 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 25 of the FAC.

26. Paragraph 26 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 26 of the FAC.

27. Paragraph 27 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 27 of the FAC.

28. Paragraph 28 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 28 of the FAC.

29. Paragraph 29 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 29 of the FAC.

30. Paragraph 30 of the FAC sets forth legal conclusions to which no response is required. To the extent a response is required, admitted that Defendants' undersigned counsel represent, *inter alia*, Serenity, Reprise, and Fein in *Ferring B.V. et al. v. Allergan, Inc. et al.*, C.A. No. 12-cv-2650-RWS (S.D.N.Y.) (the "2012 Action"). Except as expressly admitted herein, Defendants deny the allegations of Paragraph 30 of the FAC.

[redacted]

32. Paragraph 32 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 32 of the FAC.

33. Paragraph 33 of the FAC sets forth legal conclusions to which no response is required. Admitted that Fein is an equity participant and principal of Reprise, and that Fein is an equity participant and Chief Medical Officer of Serenity. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 33 of the FAC.

34. Paragraph 34 of the FAC sets forth legal conclusions to which no response is required. Admitted that Reprise licensed rights to the Patents in Suit to Serenity. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 34 of the FAC.

35. Paragraph 35 of the FAC sets forth legal conclusions to which no response is required. Admitted that Fein has intellectual property rights to, *inter alia*, his inventions embodied in the Patents in Suit, that Fein transferred certain intellectual property rights to Reprise, and that Reprise has entered into patent assignments and/or licenses with Serenity and Allergan. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 35 of the FAC.

36. Paragraph 36 of the FAC sets forth legal conclusions to which no response is required. Admitted that Fein has intellectual property rights to, *inter alia*, his inventions embodied in the Patents in Suit. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 36 of the FAC.

37. Paragraph 37 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 37 of the FAC.

38. The allegations in Paragraph 38 of the FAC purport to quote from, summarize, describe, or make allegations concerning the Three-Way Agreement. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 38 of the FAC.

39. Paragraph 39 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 39 of the FAC.

40. Paragraph 40 of the FAC sets forth legal conclusions to which no response is required. Further, the allegations in Paragraph 40 of the FAC purport to quote from, summarize, describe, or make allegations concerning the Three-Way Agreement. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 40 of the FAC.

41. Admitted that Reprise has been a party to assignments involving the Patents in Suit. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 41 of the FAC.

42. Denied.

43. Admitted that Reprise has entered into certain agreements with Serenity and Allergan. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 43 of the FAC.

44. Paragraph 44 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 44 of the FAC.

45. Paragraph 45 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 45 of the FAC.

46. The allegations in Paragraph 46 of the FAC purport to quote from, summarize, describe, or make allegations concerning certain assignments between Fein and Reprise. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 46 of the FAC.

47. Paragraph 47 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 47 of the FAC.

48. Paragraph 48 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 48 of the FAC.

49. Paragraph 49 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 49 of the FAC.

50. Paragraph 50 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 50 of the FAC.

51. Paragraph 51 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 51 of the FAC.

52. Paragraph 52 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 52 of the FAC.

53. Paragraph 53 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 53 of the FAC.

THE PATENTS IN SUIT

54. Defendants admit that a copy of what purports to be the ’203 patent was attached to the FAC as Exhibit C. Defendants admit the remaining allegations of Paragraph 54 of the FAC.

55. Defendants admit that a copy of what purports to be the ’321 patent was attached to the FAC as Exhibit D. Defendants admit the remaining allegations of Paragraph 55 of the FAC.

56. Defendants admit that a copy of what purports to be the ’761 patent was attached to the FAC as Exhibit E. Defendants admit the remaining allegations of Paragraph 56 of the FAC.

57. The allegations in Paragraph 57 of the FAC purport to quote from, summarize, describe, or make allegations concerning certain patent applications. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny the allegations in Paragraph 57 of the FAC.

58. The allegations in Paragraph 58 of the FAC purport to quote from, summarize, describe, or make allegations concerning certain patent applications and publications. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny the allegations in Paragraph 58 of the FAC.

59. The allegations in Paragraph 59 of the FAC purport to quote from, summarize, describe, or make allegations concerning certain patents and patent applications. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny the allegations in Paragraph 59 of the FAC.

60. Admitted.

61. Denied.

62. The allegations in Paragraph 62 of the FAC purport to quote from, summarize, describe, or make allegations concerning certain patents and patent applications. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny the allegations in Paragraph 62 of the FAC.

63. Admitted that the ’203 patent claims priority to PCT/US03/14463 (“PCT ’463”), and that PCT ’463 claims priority to Great Britain Patent Application No. 0210397.6 (“GB ’397”). Defendants deny the remaining allegations of Paragraph 63 of the FAC.

64. Admitted.

65. To the extent that Paragraph 65 of the FAC purports to summarize or describe the ’203 patent and its claims, Defendants state that such patent and claims speak for themselves, and

further that such summary or description is incomplete and, therefore, inaccurate and denied. To the extent that Paragraph 65 purports to delineate or characterize the scope of one or more patent claims, such delineations and characterizations state a conclusion of law, to which no response is required. Defendants deny the remaining allegations in Paragraph 65.

66. Admitted.

67. Admitted that the '321 patent claims priority to PCT '463, and that PCT '463 claims priority to GB '397. Defendants deny the remaining allegations of Paragraph 67 of the FAC.

68. Admitted.

69. To the extent that Paragraph 69 of the FAC purports to summarize or describe the '321 patent and its claims, Defendants state that such patent and claims speak for themselves, and further that such summary or description is incomplete and, therefore, inaccurate and denied. To the extent that Paragraph 69 purports to delineate or characterize the scope of one or more patent claims, such delineations and characterizations state a conclusion of law, to which no response is required. Defendants deny the remaining allegations in Paragraph 69.

70. Admitted.

71. Admitted that the '761 patent claims priority to GB '397. Defendants deny the remaining allegations of Paragraph 63 of the FAC.

72. Admitted.

73. To the extent that Paragraph 73 of the FAC purports to summarize or describe the '761 patent and its claims, Defendants state that such patent and claims speak for themselves, and further that such summary or description is incomplete and, therefore, inaccurate and denied. To the extent that Paragraph 73 purports to delineate or characterize the scope of one or more patent

claims, such delineations and characterizations state a conclusion of law, to which no response is required. Defendants deny the remaining allegations in Paragraph 73.

FACTUAL BACKGROUND

Nocturia and Treatment with Desmopressin

74. Admitted, on information and belief.

75. Admitted, on information and belief.

76. Admitted.

Serenity's NOCTIVA (desmopressin) Product

77. Admitted that a copy of what purports to be the March 3, 2017 letter from Hylton V. Joffe to Serenity was attached to the FAC as Exhibit F. Defendants admit the remaining allegations of Paragraph 77 of the FAC.

78. Admitted that the FDA granted final approval for Serenity's NDA on March 3, 2017. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 78 of the FAC.

79. Admitted.

Ferring's Long History with Desmopressin

80. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 80 of the FAC and, therefore, deny them.

81. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 81 of the FAC and, therefore, deny them.

82. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 82 of the FAC and, therefore, deny them.

83. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 83 of the FAC and, therefore, deny them.

84. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 84 of the FAC and, therefore, deny them.

Ferring's NOCDURNA

85. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 82 of the FAC and, therefore, deny them.

86. Admitted, on information and belief.

87. Admitted that Serenity's NDA was reviewed by the Division of Bone, Reproductive and Urologic Products ("DBRUP"), and that the review of NDA No. 022517 ("Ferring's NDA") was originally assigned to the Division of Metabolism and Endocrinology Products ("DMEP") of the FDA. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 87 of the FAC and, therefore, deny them.

88. Admitted that Ferring submitted a Citizen Petition to the FDA on November 22, 2016 ("Ferring's Citizen Petition") and that a copy of what purports to be Ferring's Citizen Petition was attached to the FAC as Exhibit G. The allegations in Paragraph 88 of the FAC purport to quote from, summarize, describe, or make allegations concerning Ferring's Citizen Petition. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 88 of the FAC.

89. Admitted that the FDA approved Serenity's NDA and denied Ferring's Citizen Petition on March 3, 2017, and that a copy of what purports to be the FDA's March 3, 2017 denial of Ferring's Citizen Petition (the "Janet Woodcock Letter") was attached to the FAC as Exhibit H.

The allegations in Paragraph 89 of the FAC purport to quote from, summarize, describe, or make allegations concerning the Janet Woodcock Letter. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 89 of the FAC.

90. The allegations in Paragraph 90 of the FAC purport to quote from, summarize, describe, or make allegations concerning the Janet Woodcock Letter. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 90 of the FAC and, therefore, deny them.

91. The allegations in Paragraph 91 of the FAC purport to quote from, summarize, describe, or make allegations concerning the Janet Woodcock Letter. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 91 of the FAC and, therefore, deny them.

[redacted]

[redacted]

SUBJECT MATTER JURISDICTION

99. Paragraph 99 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 99 of the FAC.

The Extensive Litigation History between the Parties

100. Admitted that at least one of Defendants is a party to the litigations addressed in subsections (i) to (iii) of Paragraph 100 of the FAC. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 100 of the FAC.

101. The allegations Paragraph 101 of the FAC concerning Defendants' "course of conduct" and "belie[f] that NOCDURNA is covered by the claims of the Patents in Suit" sets forth legal conclusions to which no response is required. Admitted that the U.S. Patent and Trademark Office ("PTO") duly issued U.S. Patent Application No. 13/378,778 (the "'778 Application") as U.S. Patent No. 9,539,302 (the "'302 patent"), that the '302 patent lists Dr. Fein as the sole inventor, and that a copy of what purports to be the July 5, 2016 Response to Office Action from the prosecution of the '778 Application was attached to the FAC as Exhibit J. To the extent that Paragraph 101 of the FAC purports to quote from, summarize, describe, or make allegations concerning Exhibit J, Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such document and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 101 of the FAC.

102. Admitted that a copy of what purports to be a letter dated October 7, 2016 from Allergan and Reprise to the EPO was attached to the FAC as Exhibit K, that a copy of what purports to be a letter dated September 12, 2011 from Allergan to the EPO was attached to the FAC as Exhibit L, and that a copy of what purports to be a letter dated December 20, 2011 from Allergan and Reprise to the EPO was attached to the FAC as Exhibit M. The allegations in Paragraph 102 of the FAC purport to quote from, summarize, describe, or make allegations concerning Exhibits K, L, and M. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore,

inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 102 of the FAC.

NOCDURNA and FDA Approval

103. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 103 of the FAC and, therefore, deny them.

104. Admitted that Ferring's NDA was approved on June 21, 2018. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 104 of the FAC and, therefore, deny them.

[redacted]

106. Paragraph 106 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 106 of the FAC and, therefore, deny them.

The Adverse Legal Interests Between the Parties

107. Paragraph 107 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 107 of the FAC.

108. Paragraph 108 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 108 of the FAC.

109. Paragraph 109 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 109 of the FAC.

COUNT I
(Declaratory Judgment of Invalidity of the Patents in Suit Under 35 U.S.C. § 102)

110. Defendants incorporate by reference herein their responses to Paragraphs 1 to 109 of the FAC as if fully restated herein.

111. Paragraph 111 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 111 of the FAC.

112. Paragraph 112 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 112 of the FAC.

113. Denied.

114. Paragraph 114 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 114 of the FAC.

115. Denied.

116. Denied.

117. Denied.

COUNT II
(Declaratory Judgment of Invalidity of the Patents in Suit for Lack of Enablement Under 35 U.S.C. § 112, ¶ 1)

118. Defendants incorporate by reference herein their responses to Paragraphs 1 to 109 of the FAC as if fully restated herein.

119. Paragraph 119 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 119 of the FAC.

120. Paragraph 120 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 120 of the FAC.

121. Paragraph 121 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 121 of the FAC.

122. Paragraph 122 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 122 of the FAC.

123. Paragraph 123 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 123 of the FAC.

124. Denied that Fein admitted that the Patents in Suit are not enabled. Admitted that a copy of what purports to be the January 22, 2016, Request for Continued Examination from the prosecution of the '778 Application was attached to the FAC as Exhibit N. The allegations in Paragraph 124 of the FAC purport to quote from, summarize, describe, or make allegations concerning Exhibit N. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and

their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 124 of the FAC.

125. Admitted that Fein submitted a declaration during prosecution of the '778 Application on June 30, 2018, and that a copy of what purports to be the July 20, 2016 Office Action from the prosecution of the '778 Application was attached to the FAC as Exhibit O. The allegations in Paragraph 125 of the FAC purport to quote from, summarize, describe, or make allegations concerning certain patent prosecution documents. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 125 of the FAC.

126. Denied.

COUNT III
(Declaratory Judgment of Invalidity of the Patents in Suit for Inadequate Written Description Under 35 U.S.C. § 112, ¶ 1)

127. Defendants incorporate by reference herein their responses to Paragraphs 1 to 109 of the FAC as if fully restated herein.

128. Paragraph 128 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 128 of the FAC.

129. Paragraph 129 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 129 of the FAC.

130. Defendants incorporate by reference herein their responses to Paragraphs 120 to 125 of the FAC as if fully restated herein. Paragraph 130 of the FAC sets forth legal conclusions

to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 130 of the FAC.

131. Denied.

COUNT IV
(Declaratory Judgment of Invalidity of the Patents in Suit Under 35 U.S.C. § 112, ¶ 2)

132. Defendants incorporate by reference herein their responses to Paragraphs 1 to 109 of the FAC as if fully restated herein.

133. Denied.

134. Paragraph 134 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 134 of the FAC.

135. Paragraph 135 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 135 of the FAC.

136. Paragraph 136 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 136 of the FAC.

137. Denied.

COUNT V
(Declaratory Judgment of Unenforceability of the Patents in Suit)

138. Defendants incorporate by reference herein their responses to Paragraphs 1 to 109 of the FAC as if fully restated herein.

139. Paragraph 139 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 139 of the FAC.

140. Paragraph 140 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 140 of the FAC.

141. Admitted that Fein signed a Combined Declaration and Power of Attorney for Sole Inventor ("Combined Declaration") on March 19, 2004, that Fein is the sole inventor of the inventions claimed in the '100 Application, and that a copy of what purports to be the Combined Declaration from the prosecution of the application that issued as the '761 patent was attached to the FAC as Exhibit P. The allegations in Paragraph 141 of the FAC purport to quote from, summarize, describe, or make allegations concerning the Combined Declaration for the '761 patent. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 141 of the FAC.

142. Admitted that Fein submitted the Combined Declaration on March 29, 2004 during prosecution of the '761 patent, that Fein submitted the Combined Declaration on July 26, 2007 during prosecution of the '203 patent, that Fein submitted the Combined Declaration on July 15, 2008 during prosecution of the '321 patent, and that a copy of what purports to be the Combined Declaration for the '203 and '321 patents was attached to the FAC as Exhibits Q and R, respectively. To the extent that Paragraph 142 of the FAC purports to quote from, summarize, describe, or make allegations concerning Exhibits P, Q, and R, Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs'

characterizations of such document and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 142 of the FAC.

143. Paragraph 143 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 143 of the FAC.

144. Paragraph 144 of the FAC sets forth legal conclusions to which no response is required. Admitted that the Patents in Suit include an Example 8, that a copy of what purports to be the April 8, 2008, Amendment and Response to Office Action in the file history for the '761 patent was attached to the FAC as Exhibit S, that a copy of what purports to be the July 15, 2008, Preliminary Amendment in the file history for the '321 patent was attached to the FAC as Exhibit T, and that a copy of what purports to be the Response to Office Action in the reexamination of the '203 patent was attached to the FAC as Exhibit U. The allegations in Paragraph 144 of the FAC purport to quote from, summarize, describe, or make allegations concerning the Patents in Suit, the Ferring CS009 clinical study protocol, and Exhibits S, T, and U. Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and accordingly Defendants deny Plaintiffs' characterizations of such documents and their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 144 of the FAC.

145. Paragraph 145 of the FAC sets forth legal conclusions to which no response is required. To the extent that Paragraph 145 of the FAC purports to quote from, summarize, describe, or make allegations concerning GB '397, PCT '463, or the Combined Declaration, Defendants state that such documents speak for themselves, and further that such quotes, summaries, descriptions, and allegations are incomplete and, therefore, inaccurate, and

accordingly Defendants deny Plaintiffs' characterizations of such document and their contents. To the extent a response is required, Defendants deny the allegations of Paragraph 145 of the FAC.

146. Paragraph 146 of the FAC sets forth legal conclusions to which no response is required. Admitted that the Patents in Suit include an Example 8. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 146 of the FAC.

147. Paragraph 147 of the FAC sets forth legal conclusions to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 147 of the FAC.

148. Denied.

COUNT VI
(Declaratory Judgment of Noninfringement of the Patents in Suit)

149. Defendants incorporate their answers to Paragraphs 1 to 109 as set forth above.

150. Admitted.

151. Denied.

152. Denied.

PRAYER FOR RELIEF

153. Defendants deny that Plaintiffs are entitled to any of the relief they seek in Paragraphs (a) through (n) of their Prayer for Relief, or any relief whatsoever. Defendants deny any and all remaining allegations in Plaintiffs' Prayer for Relief.

AFFIRMATIVE DEFENSES

154. Subject to the responses above, and without assuming any burden other than that imposed by operation of law, Defendants allege and assert the following defenses, affirmative or otherwise, in response to the allegations of Plaintiffs' FAC. In addition to the defenses described below, Defendants expressly reserve the right to assert any other legal or equitable defenses that

may now exist or in the future be available based on discovery and further investigation in this case.

FIRST DEFENSE – VALIDITY

155. The Patents in Suit are valid and satisfy the requirements and/or conditions for patentability under Title 35, United States Code § 1, *et seq.*, including without limitation §§ 102 and/or 112.

SECOND DEFENSE – INFRINGEMENT

156. On information and belief, as set forth in Counts I-IV of the Counterclaims below, Ferring's NOCDURNA product, and the use thereof, infringes at least one claim of at least the '203 and '321 patents.

THIRD DEFENSE – FAILURE TO STATE A CLAIM

157. Plaintiffs' FAC fails, in whole or in part, to state a claim upon which relief may be granted, at least for the reason that Ferring fails to provide factual allegations sufficient to support the relief it seeks.

FOURTH DEFENSE – EQUITABLE DOCTRINES

158. On information and belief, Plaintiffs are barred, in whole or in part, by the equitable doctrines of laches, waiver, acquiescence, unclean hands, and/or estoppel from asserting that any claim of the Patents in Suit is invalid and/or unenforceable, based on least on their previous submissions and representations made to this Court in the 2012 Action.

FIFTH DEFENSE – SUIT BARRED

159. On information and belief, Plaintiffs are barred, in whole or in part, by findings of fact and/or conclusions of law in the 2012 Action, including, *inter alia*, this Court's decisions dismissing Ferring's inventorship claims (D.I. 190) and dismissing Ferring's Rule 52(c) motion (D.I. 342).

SIXTH DEFENSE – NO ATTORNEYS' FEES

160. Plaintiffs cannot prove that this is an exceptional case justifying an award of attorneys' fees against Defendants under 35 U.S.C. § 285 or otherwise.

SEVENTH DEFENSE – NO INJUNCTIVE RELIEF

161. Plaintiffs cannot prove that this case justifies issuing the injunctive relief requested in Paragraphs (d), (h), and (l) of Plaintiffs' Prayer for Relief.

OTHER APPLICABLE DEFENSES

162. Defendants expressly reserve the right to assert any other legal or equitable defenses to which they are shown to be entitled.

COUNTERCLAIMS

For their Counterclaims against Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals, Inc. (collectively "Ferring"), Counterclaim-Plaintiffs Serenity Pharmaceuticals, LLC ("Serenity"), Reprise Biopharmaceutics, LLC ("Reprise"), and Avadel Specialty Pharmaceuticals, LLC ("Avadel") (collectively, "Counterclaimants") allege as follows.

NATURE OF THE SUIT

1. This is an action for patent infringement and related claims arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 7,405,203 (the "'203 patent"), and 7,579,321 (the "'321 patent") (collectively with U.S. Patent No. 7,799,761, the "Patents in Suit"), as well as related claim for declaratory judgment of non-infringement arising under the trademark laws of the United States, Title 15, United States Code. This action relates to Ferring's New Drug Application ("NDA") No. 022517 for NOCDURNA (desmopressin acetate) sublingual tablets ("Ferring's NDA"), as well as Counterclaimants' use of the trademark NOCTIVA for "Pharmaceutical preparations for the treatment of nocturia" (the "*NOCTIVA* mark").

2. Counterclaimants seek judgment that: (a) Ferring has infringed the '203 and '321 patents; (b) that Ferring's infringement of the '203 and '321 patents has been willful; and (c) Counterclaimants' use of the *NOCTIVA* mark does not infringe any rights of Ferring.

THE PARTIES

3. Serenity is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 105 Hawk Court, Milford, PA 18327.

4. Serenity is an exclusive licensee of the '203 and '321 patents, with the right to enforce the '203 and '321 patents.

5. Serenity is the lawful owner of all right, title, and interest in the *NOCTIVA* mark.

6. Reprise is a limited liability company organized and existing under the laws of the State of New York with its principal place of business located at 120 North Main Street, Suite 400, New City, New York 10956.

7. Reprise is the lawful owner of all right, title, and interest in the '203 and '321 patents, including the right to sue and to recover for infringement thereof.

8. Avadel is a limited liability company organized and existing under the laws of Delaware, with its principal place of business located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005.

9. Avadel is an exclusive sublicensee of the '203 and '321 patents, with the right to enforce the '203 and '321 patents.

10. Avadel is an exclusive licensee of the *NOCTIVA* mark, which is used in commerce.

11. Upon information and belief, Ferring B.V. is a private limited liability company having its registered office at Polarisavenue 144, 2132 JX Hoofddorp, The Netherlands.

12. Upon information and belief, Ferring B.V. claims to be the owner of a United States trademark registration for the NOCDURNA mark and all rights associated therewith.

13. Upon information and belief, Ferring International Center S.A. is a private limited liability company having its offices at Ch. de la Vergognausaz 50, 1162 Saint-Prex, Switzerland.

14. Upon information and belief, Ferring International Center S.A. is a sister company of Ferring B.V.

15. Upon information and belief, Ferring Pharmaceuticals Inc. is a private corporation organized under the laws of the State of Delaware, having its principal place of business at 4 Gatehall Dr., 3rd Floor, Parsippany, New Jersey 07054 and formerly having its principal place of business in Tarrytown, New York.

16. Upon information and belief, Ferring Pharmaceuticals, Inc. is a wholly-owned subsidiary of Ferring B.V.

17. Upon information and belief, Ferring B.V. has licensed its rights in the NOCDURNA mark to Ferring Pharmaceuticals Inc.

JURISDICTION AND VENUE

18. These Counterclaims arise under the patent laws of the United States, Title 35, United States Code, as well as the trademark laws of the United States, Title 15, United States Code. This Court has original jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

19. Ferring is subject to personal jurisdiction in this Judicial District because Ferring has availed itself of the rights and privileges of this forum by previously asserting claims against Serenity and Reprise in this District in Action No. 12 Civ. 2650 (RWS).

20. On information and belief, this Court also has personal jurisdiction over Ferring because, *inter alia*, Ferring maintains continuous, systematic, and pervasive contacts with this Judicial District. Either directly, or through its subsidiaries, agents, and/or affiliates, Ferring has conducted and continues to conduct business in this judicial district, including, on information and

belief, by marketing and selling drug products throughout the United States and in the Southern District of New York.

21. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 1400.

22. Venue is also proper and convenient in this District because Ferring selected this venue to assert claims against Serenity and Reprise in Action No. 12 Civ. 2650 (RWS).

THE ASSERTED PATENTS

THE '203 PATENT

23. The '203 patent was duly and legally issued on July 29, 2008, naming Dr. Seymour Fein as its sole inventor. Reprise is the lawful owner of all right, title, and interest in the '203 patent, titled "PHARMACEUTICAL COMPOSITIONS INCLUDING LOW DOSAGES OF DESMOPRESSIN," including the right to sue and to recover for infringement thereof. Serenity is an exclusive licensee of the '203 patent, with the right to enforce the '203 patent. Avadel is an exclusive sublicensee of the '203 patent, with the right to enforce the '203 patent. The '203 patent is listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") as covering *NOCTIVA*, which is the subject of approved NDA No. 201656.

THE '321 PATENT

24. The '321 patent was duly and legally issued on August 25, 2009, naming Dr. Seymour Fein as its sole inventor. Reprise is the lawful owner of all right, title, and interest in the '321 patent, titled "PHARMACEUTICAL COMPOSITIONS INCLUDING LOW DOSAGES OF DESMOPRESSIN," including the right to sue and to recover for infringement thereof. Serenity is an exclusive licensee of the '321 patent, with the right to enforce the '321 patent. Avadel is an exclusive sublicensee of the '321 patent, with the right to enforce the '321 patent. The '203 patent is listed in the Orange Book as covering *NOCTIVA*, which is the subject of approved NDA No. 201656.

FACTUAL BACKGROUND

25. Desmopressin, a synthetic analog of the hormone arginine vasopressin, is used to treat a variety of disorders including central diabetes insipidus, nocturnal enuresis, and nocturia.

26. In the early 1990s, Dr. Seymour Fein, a board-certified internist and medical oncologist, came up with the idea that desmopressin could be effective in much lower doses than previously known.

27. In 2001, during the course of his consulting work with Ferring, Dr. Fein communicated his discovery of low-dose desmopressin to Ferring and helped design clinical studies to test his ideas. Dr. Fein also suggested that desmopressin could be delivered via a sublingual dosage form, which would improve its bioavailability and allow for a greater percentage of desmopressin in the formulation to reach the bloodstream.

28. Ferring initially asked Dr. Fein to retroactively assign his desmopressin-related inventions to Ferring, and then terminated Dr. Fein's consultancy when he refused to do so.

29. Subsequently, Dr. Fein obtained patent protection for his desmopressin-related inventions embodied in the Patents in Suit.

30. Reprise and Serenity obtained an interest in Dr. Fein's inventions embodied in the Patents in Suit.

31. In 2012, Ferring filed suit in this District to claim ownership of the Patents in Suit in *Ferring B.V. et al. v. Allergan, Inc. et al.*, C.A. No. 12-cv-2650-RWS (S.D.N.Y.) (the "2012 Action"). In the 2012 Action, Ferring alleged, *inter alia*, that the Patents in Suit included "significant inventive contributions" of Ferring's own employees. (*See, e.g.*, C.A. No. 12-2650, D.I. 1 ¶ 103.) Ferring also sought to disgorge the $43 million that Serenity and Reprise received from their then-marketing partner in return for access to the patent rights. (*See, e.g.*, *id.* ¶ 335.)

32. On April 28, 2017, Ferring filed this suit in the District of Delaware, alleging now that the Patents in Suit were actually invalid under 35 U.S.C. §§ 102 and 112, and unenforceable for alleged inequitable conduct.

33. Subsequently, Avadel obtained an interest in the Patents in Suit and the *NOCTIVA* mark.

34. On December 20, 2017, the District of Delaware suit was transferred to this District as the above-captioned action.

SERENITY'S NDA

35. On February 4, 2016, Serenity's NDA was filed under § 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)), seeking approval to engage in the commercial manufacture, use, or sale of *NOCTIVA* (desmopressin acetate) nasal spray for the treatment of nocturia.

36. On March 3, 2017, the U.S. Food and Drug Administration ("FDA") approved Serenity's NDA, and *NOCTIVA* became the first drug to be approved for the treatment of nocturia in the United States.

FERRING'S NDA

37. Upon information and belief, on or before June 22, 2009, Ferring's NDA was filed under § 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)), seeking approval to engage in the commercial manufacture, use, or sale of NOCDURNA (desmopressin acetate) sublingual tablets for the treatment of nocturia.

[redacted]

[redacted]

39. Upon information and belief, on June 21, 2018, the FDA approved Ferring's NDA No. 022517.

40. Prior to June 21, 2018, which Ferring represented to be the FDA's nominal action date for a decision on Ferring's NDA, Serenity and Reprise repeatedly asked Ferring to produce its NDA to Serenity and Reprise on an outside counsel's eyes only basis, but Ferring refused to do so.

41. On June 5, 2018, Serenity and Reprise presented Ferring with an Application for an Order to Show Cause Why A Temporary Restraining Order Should Not Issue (the "TRO Show Cause Application").

42. On June 7, 2018, the parties appeared before the Honorable Robert W. Sweet of the U.S. District Court for the Southern District of New York to discuss Serenity and Reprise's TRO Show Cause Application.

[redacted]

THE *NOCTIVA* AND NOCDURNA MARKS

44. On April 9, 2014, an application to register the *NOCTIVA* mark was filed with the U.S. Patent and Trademark Office ("USPTO") and assigned Application Serial No. 86247669 ("*NOCTIVA* Application").

45. The *NOCTIVA* Application was filed on an intent to use basis pursuant to 15 U.S.C. § 1051(b). On or about March 3, 2017, the FDA announced the approval of *NOCTIVA* and

Serenity published a press release announcing the approval of *NOCTIVA*. Products using the *NOCTIVA* mark have been used in commerce at least as early as April 2018.

46. On August 7, 2009, Ferring filed an application with the USPTO to register the trademark NOCDURNA for "Pharmaceutical products and preparations for use in treating urological disorders and conditions" (the "NOCDURNA Mark"), which eventually was registered as Registration No. 4405021.

47. Ferring's application to register the NOCDURNA mark was filed on an intent-to-use basis but, after it failed to prove use of the mark for almost three years, it amended the basis for its application to rely on Section 44(e) of the Lanham Act (15 U.S.C. § 1126(e)) based on Ferring's European Community Trademark Registration for NOCDURNA, which allowed Ferring to register the mark without ever using the mark in commerce in the United States.

48. In correspondence dated October 2, 2014, counsel for Ferring asserted:

> [The] intended use and registration of NOCTIVA [is] likely to infringe Ferring's rights in its trademarks for NOCDURNA and NOCTURIN.[1] The applied for trademarks are confusingly similar to Ferring's trademarks. The marks look similar, sound similar, and have similar prefixes and suffixes. In addition, the goods are related and competitive, would travel through the same channels of trade, and be marketed and promoted to the same buyers and consumers. These factors are likely to cause consumers to mistakenly assume that the products are provided by the same source.

49. Contrary to Ferring's assertions, the *NOCTIVA* and NOCDURNA Marks look and sound different. Moreover, the *NOCTIVA* and NOCDURNA Marks cover prescription drug products, which are sold through highly-regulated, sophisticated channels. For at least these reasons, it is unlikely that consumers will mistakenly assume that the products are provided by the same source.

[1] Ferring's registration of NOCTURIN was cancelled on February 26, 2016, due to Ferring's failure to prove use of the mark in the United States. The NOCTURIN mark therefore is not at issue in this proceeding.

50. On November 25, 2014, Ferring B.V. filed an opposition in the Trademark Trial and Appeal Board ("TTAB") against the *NOCTIVA* Application, which eventually was consolidated under Opposition No. 91219485 ("*NOCTIVA* Opposition").

51. The *NOCTIVA* Opposition, as well as Ferring's threats regarding the use of the *NOCTIVA* Mark, have created uncertainty regarding Counterclaimants' continued use of the *NOCTIVA* Mark on and in connection with their *NOCTIVA* products.

52. The *NOCTIVA* Opposition has been suspended repeatedly pending the outcome of the FDA's review of Ferring's NDA.

53. On information and belief, following the FDA's approval of Ferring's NDA on June 21, 2018, Ferring intends to commence litigation seeking to interfere with Counterclaimants' use of the *NOCTIVA* Mark.

54. In view of Ferring's past threats and the FDA's recent approval of Ferring's NDA, Counterclaimants are in need of a declaration that their continued use of the *NOCTIVA* Mark does not infringe any trademark rights owned by Ferring and does not constitute unfair competition under any federal or state statute.

COUNT I

(INFRINGEMENT OF U.S. PATENT NO. 7,405,203)

55. Counterclaimants incorporate by reference and reallege paragraphs 1 through 54 above as though fully restated herein.

56. An actual and justiciable case or controversy exists between Counterclaimants and Ferring regarding whether Ferring's manufacture, use, importation, sale, and/or offer for sale of its NOCDURNA products infringes, contributes to the infringement of, and/or induces the infringement of one or more claims of the '203 patent.

57. Ferring's NOCDURNA products, or the use or manufacture thereof, are covered by one or more claims of the '203 patent, including but not limited to independent claim 1, which recites, *inter alia*, a method of treating nocturia, primary nocturnal enuresis, or incontinence, or for inducing voiding postponement, said method comprising administering to a patient in need thereof a pharmaceutical composition comprising a dose of desmopressin sufficient to achieve and maintain certain plasma/serum concentrations, and various dependent claims therefrom.

58. Ferring's commercial manufacture, use, importation, sale, and/or offer for sale of its NOCDURNA products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '203 patent under 35 U.S.C. §§ 271(a)-(c).

59. Ferring's NOCDURNA products constitute a material part of the inventions covered by the claims of the '203 patent.

60. On information and belief, Ferring knows that its NOCDURNA products are especially made or especially adapted for use in the infringement of one or more claims of the '203 patent.

61. On information and belief, Ferring has had and continues to have knowledge that there is no substantial non-infringing use for its NOCDURNA products.

62. The administration of Ferring's NOCDURNA products by any Healthcare Providers and patients, for the treatment of nocturia, will directly infringe one or more claims of the '203 patent.

63. Ferring's NOCDURNA product label will explicitly instruct Healthcare Providers and patients to use Ferring's NOCDURNA products in a manner that will directly infringe one or more claims of the '203 patent, including but not limited to independent claim 1, which recites, *inter alia*, a method of treating nocturia, primary nocturnal enuresis, or incontinence, or for

inducing voiding postponement, said method comprising administering to a patient in need thereof a pharmaceutical composition comprising a dose of desmopressin sufficient to achieve and maintain certain plasma/serum concentrations, and various dependent claims therefrom.

64. Ferring will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '203 patent. Since at least April 5, 2012, when Ferring filed the 2012 Action, Ferring has acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '203 patent.

65. Ferring intends to cause direct infringement by others, *e.g.*, Healthcare Providers and patients.

66. Ferring has and will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Ferring's NOCDURNA product label, to use Ferring's NOCDURNA products in a manner that directly infringements one or more claims of the '203 patent. Thus, Ferring will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '203 patent, and Ferring will affirmatively and specifically intend to cause direct infringement.

67. Ferring has been aware of the existence of the '203 patent since at least as early as April 5, 2012, when Ferring filed the 2012 Action. Ferring is also aware that the PTO confirmed the validity of the '203 patent on April 12, 2011 by issuing Ex Parte Reexamination Certificate No. US 7,405,203 C1.

68. Ferring has no reasonable basis for believing that Ferring's NOCDURNA products will not infringe the '203 patent or that the '203 patent is invalid or unenforceable, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

69. Unless Ferring is enjoined by the Court, Counterclaimants will be substantially and irreparably harmed by Ferring's infringement of the '203 patent. Counterclaimants do not have an adequate remedy at law. The balance of hardships favors Counterclaimants, and the public interest would not be disserved by the Court enjoining Ferring.

COUNT II

(WILLFUL INFRINGEMENT OF U.S. PATENT NO. 7,405,203)

70. Counterclaimants incorporate by reference and reallege paragraphs 1 through 69 above as though fully restated herein.

71. Ferring has been aware of the existence of the '203 patent since at least as early as April 5, 2012 when Ferring filed the 2012 Action. Ferring is also aware that the PTO confirmed the validity of the '203 patent on April 12, 2011 by issuing Ex Parte Reexamination Certificate No. US 7,405,203 C1.

72. Ferring has no reasonable basis for believing that Ferring's NOCDURNA products will not infringe the '203 patent or that the '203 patent is invalid or unenforceable. Ferring has nonetheless continued its infringing activities. As a result, Ferring has acted recklessly and continues to willfully, wantonly, and deliberately engage in acts of infringement of the '203 Patent, warranting an award to Counterclaimants of enhancement of any damages to be awarded under 35 U.S.C. § 284.

COUNT III

(INFRINGEMENT OF U.S. PATENT NO. 7,579,321)

73. Counterclaimants incorporate by reference and reallege paragraphs 1 through 72 above as though fully restated herein.

74. An actual and justiciable case or controversy exists between Counterclaimants and Ferring regarding whether Ferring's manufacture, use, importation, sale, and/or offer for sale of

its NOCDURNA products infringes, contributes to the infringement of, and/or induces the infringement of one or more claims of the '321 patent.

75. Ferring's NOCDURNA products, or the use or manufacture thereof, are covered by one or more claims of the '321 patent, including but not limited to: independent claim 1, which recites, *inter alia*, a method of inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia comprising delivering to the bloodstream of the patient a certain amount of desmopressin by intranasal, transdermal, intradermal, transmucosal, or conjunctival administration, said amount being therapeutically effective to produce an antidiuretic effect over a certain time period, and various dependent claims therefrom; and independent claim 8, which recites, *inter alia*, a method of inducing voiding postponement comprising administering to a patient an amount of desmopressin sufficient to produce in the patient a certain urine osmolality over a certain time period, and various dependent claims therefrom.

76. Ferring's commercial manufacture, use, importation, sale, and/or offer for sale of Ferring's NOCDURNA products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '321 patent under 35 U.S.C. §§ 271(a)-(c).

77. Ferring's NOCDURNA products constitute a material part of the inventions covered by the claims of the '321 patent.

78. On information and belief, Ferring knows that its NOCDURNA products are especially made or especially adapted for use in the infringement of one or more claims of the '321 patent.

79. On information and belief, Ferring has had and continues to have knowledge that there is no substantial non-infringing use for its NOCDURNA products.

80. The administration of Ferring's NOCDURNA products by any Healthcare Providers and patients, for the treatment of nocturia, will directly infringe one or more claims of the '321 patent.

81. Ferring's NOCDURNA product label will explicitly instruct Healthcare Providers and patients to use Ferring's NOCDURNA products in a manner that will directly infringe one or more claims of the '321 patent, including but not limited to: independent claim 1, which recites, *inter alia*, a method of inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia comprising delivering to the bloodstream of the patient a certain amount of desmopressin by intranasal, transdermal, intradermal, transmucosal, or conjunctival administration, said amount being therapeutically effective to produce an antidiuretic effect over a certain time period, and various dependent claims therefrom; and including but not limited to independent claim 8, which recites, *inter alia*, a method of inducing voiding postponement comprising administering to a patient an amount of desmopressin sufficient to produce in the patient a certain urine osmolality over a certain time period, and various dependent claims therefrom.

82. Ferring will actively induce others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '321 patent. Since at least April 5, 2012, when Ferring filed the 2012 Action, Ferring has acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '321 patent.

83. Ferring intends to cause direct infringement by others, *e.g.*, Healthcare Providers and patients.

84. Ferring has and will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Ferring's NOCDURNA product

label, to use Ferring's NOCDURNA products in a manner that directly infringements one or more claims of the '321 patent. Thus, Ferring will aid, abet, urge, or encourage others including, *e.g.*, Healthcare Providers and patients, to directly infringe one or more claims of the '321 patent, and Ferring will affirmatively and specifically intend to cause direct infringement.

85. Ferring has no reasonable basis for believing that Ferring's NOCDURNA products will not infringe the '321 patent or that the '321 patent is invalid or unenforceable, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

86. Unless Ferring is enjoined by the Court, Counterclaimants will be substantially and irreparably harmed by Ferring's infringement of the '321 patent. Counterclaimants do not have an adequate remedy at law. The balance of hardships favors Counterclaimants, and the public interest would not be disserved by the Court enjoining Ferring.

COUNT IV

(WILLFUL INFRINGEMENT OF U.S. PATENT NO. 7,579,321)

87. Counterclaimants incorporate by reference and reallege paragraphs 1 through 86 above as though fully restated herein.

88. Ferring has been aware of the existence of the '321 patent since at least as early as April 5, 2012 when Ferring filed the 2012 Action.

89. Ferring has no reasonable basis for believing that Ferring's NOCDURNA products will not infringe the '321 patent or that the '321 patent is invalid or unenforceable. Ferring has nonetheless continued its infringing activities. As a result, Ferring has acted recklessly and continues to willfully, wantonly, and deliberately engage in acts of infringement of the '321 Patent, warranting an award to Counterclaimants of enhancement of any damages to be awarded under 35 U.S.C. § 284.

COUNT V

(DECLARATORY JUDGMENT OF NO TRADEMARK INFRINGEMENT)

90. Counterclaimants incorporate by reference and reallege paragraphs 1 through 89 above as though fully restated herein.

91. Ferring has asserted that the use of the *NOCTIVA* Mark on and in connection with the *NOCTIVA* product constitutes trademark infringement.

92. As a result, an actual and justiciable case or controversy exists between Counterclaimants and Ferring regarding whether use of the *NOCTIVA* Mark constitutes infringement of the NOCDURNA Mark.

93. Serenity therefore seeks a declaration from this Court that its use of the *NOCTIVA* Mark on and in connection with its desmopressin nasal spray does not constitute infringement or unfair competition under the Lanham Act or any other applicable statute or law.

COUNTERCLAIMANTS' PRAYER FOR RELIEF

Wherefore, Counterclaimants respectfully request that the Court enter judgment in their favor and against Ferring on the claims set forth above by

A. Adjudging that Ferring has infringed one or more claims of at least the '203 and '321 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Ferring's NOCDURNA products will infringe, induce infringement of, and/or contribute to the infringement of one or more claims of at least the '203 and '321 patents;

B. If products infringing the '203 and '321 patents are marketed, adjudging and ordering Ferring to pay Counterclaimants damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial;

C. Adjudging that Ferring has willfully infringed one or more claims of at least the '203 and '321 patents and awarding to Counterclaimants enhancement of any damages awarded under 35 U.S.C. § 284.

D. Adjudging that each and every claim of the Patents in Suit is valid, enforceable, and satisfies the requirements and/or conditions for patentability under Title 35, United States Code § 1, *et seq.*, including without limitation §§ 102 and/or 112;

E. Adjudging and declaring that Counterclaimants' conduct, including their use of the *NOCTIVA* Mark on and in connection with the *NOCTIVA* product, does not constitute infringement or unfair competition under the Lanham Act or any other statute or law;

F. Adjudging and declaring that Counterclaimants are entitled to continue to sell the *NOCTIVA* product under the *NOCTIVA* Mark;

G. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. § 283 and Rule 65, Fed. R. Civ. P., Ferring, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of NDA No. 22517, including Ferring's NOCDURNA products or any other drug product that infringes the '203 and '321 patents;

H. Declaring this an exceptional case and awarding Counterclaimants their attorneys' fees and costs, as provided by 35 U.S.C. § 285;

I. Awarding Counterclaimants their costs in this action;

J. Awarding Counterclaimants their attorneys' fees pursuant to 15 U.S.C. § 1117(a); and

K. Awarding Counterclaimants such other and further relief as this Court may deem just and proper.

Dated: June 28, 2018
New York, New York

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 28th day of June, 2018 the foregoing document was served upon the following counsel for Ferring in the manner indicated:

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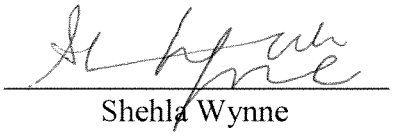

Shehla Wynne